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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,561

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James F. Zucherman

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

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3733

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DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/790,561	Applicant(s) ZUCHERMAN ET AL.	
	Examiner JERRY CUMBERLEDGE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 48-61 are rejected under 35 U.S.C. 102(e) as being anticipated by
Howland et al. (US Pat. 5,496,318).

Howland et al. disclose an implant to be implanted between adjacent first and second spinous processes (Fig. 12) , the implant comprising: a planar unitary body (Fig. 12) having two ends and first and second opposed sides extending therebetween spaced apart a lateral distance (Fig. 12, ref. 130 and opposite analogous side); a first leg extending from the first end along the second side (Fig. 12, ref. 120); a second leg (Fig. 12, another ref. 120) extending from the second end along the first side; a first saddle (Fig. 10, portion seated over spinous process) disposed at the first end between the first leg and the first side so as to receive the first spinous process when the implant is implanted; the first saddle extending at least half of the lateral distance across the body in a direction from the first side toward the second side (Fig. 12); a second saddle (Fig. 10, opposite portion seated over spinous process) disposed at the second end between the second leg and the second side so as to receive the second spinous

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process when implanted (Fig. 10); a first fastener (Fig. 10, upper loop of ref. 124) that encloses the first saddle securing the first spinous process to the first saddle; and a second fastener (Fig. 10, lower loop of ref. 124) that encloses the second saddle for securing the second spinous process to the second saddle (Fig. 10). The first fastener is separate from said second fastener (Fig. 10, since they are spaced at the top and bottom of the device). At least one of the first or second fasteners comprises a tether (Fig. 10). The first and second spinous processes being adjacent spinous processes, wherein the planar body, when implanted, extends in compression between the first spinous process at the first end and the second spinous process at the second end so as to distract the adjacent spinous processes (Fig. 10).

Howland et al. disclose an implant for use as an interspinous process implant between a first spinous process and a second spinous process, the implant comprising: a planar unitary body (Fig. 12) having a two ends (Fig. 12, ref. 130 and opposite end) that each define a saddle (Fig. 10, portions that sit on spinous processes), the planar unitary body having a central longitudinal axis disposed generally transverse to the first end and extending through the first and second saddles (Fig. 12); a first tether (Fig. 10, upper loop of ref. 124) that encloses the first saddle surrounding the first spinous process when the first saddle receives the first spinous process; a second tether (Fig. 10, lower portion of ref. 124) that encloses the second saddle (Fig. 10) so as to surround the second spinous process when the second saddle receives the second spinous process (Fig. 10); and wherein the planar body extends between and separates the spinous processes when the first saddle receives the first spinous

process and when the second saddle receives the second spinous process (Fig. 10).

The first tether is configured to retain the first spinous process relative to the first saddle and the second tether is configured to retain the second spinous process relative to the second saddle (Fig. 10). The device comprises multiple legs (Fig. 12, ref. 120).

Howland et al. disclose an interspinous process implant comprising: a unitary central planar body (Fig. 12) with first and second saddles located on opposite first and second sides of the planar body respectively (Fig. 10, portions that sit on spinous processes) and configured to receive adjacent spinous processes (Fig. 10), the first saddle extending across the planar body in a direction from the first side toward the second side (Fig. 12); the second saddle extending across the planar body in a direction from the second side toward the first side such that at least a portion of the second saddle laterally overlaps at least a portion of the first saddle (Fig. 11, considering the overlapping, mating portions of the device to be different portions of the saddles); and the interspinous process implant having at least one tether secured to at least one saddle so as to retain the interspinous process implant between the interspinous process and maintain separation between the interspinous processes (Fig. 10, ref. 124). The planar body is configured to distract the adjacent spinous processes (Fig. 10).

An implant for relieving pain associated with a spine comprising: a unitary planar body (Fig. 12) having a continuous surface (Fig. 12) positionable between two adjacent spinous processes (Fig. 10), the planar body having a lateral width (Fig. 12) and two ends (Fig. 12, end near ref. 130 and opposite end); the first end of the planar body defining a first saddle configured to receive the first spinous process (Fig. 10, upper

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portion that sits on spinous process); the second end of the planar body defining a second saddle configured to receive the second spinous process (Fig. 10, lower portion that sits on lower spinous process); the first saddle extending at least half of the lateral width across the planar body (Fig. 12); the second saddle extending at least half of the lateral width across the planar body (Fig. 12) such that at least a portion of the second saddle laterally overlaps at least a portion of the first saddle (Fig. 11, considering the overlapping, mating portions of the device to be different portions of the saddles); a first fastener (Fig. 10, upper loop of ref. 124) that encloses the first saddle for retaining the first spinous process in the first saddle; and a second fastener (Fig. 10, lower loop of ref. 124) that encloses the second saddle for retaining the second spinous process in the second saddle (Fig. 10). The first saddle is associated with a first leg and first side of the planar body and the second saddle is associated with a second leg and a second side of the planar body (Fig. 10). The fasteners are secured through bores in the legs of the device (Fig. 11, near ref. 106). The first fastener forms a loop around the first saddle for securing the first spinous process to the first saddle and a second fastener forms a loop around the second saddle for securing the second spinous process to the second saddle (Fig. 10). The second saddle extends at least half of the lateral distance across the body in a direction from the second side to the first side (Fig. 12).

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733